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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,885	07/30/2003	Karla Weaver	10123/00301	7939
30636	7590	11/30/2005	EXAMINER	
FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			STIGELL, THEODORE J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/630,885	Applicant(s) WEAVER ET AL.	
	Examiner Theodore J. Stigell	Art Unit 3763	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species B (Figure 4) in the reply filed on October 6, 2005 is acknowledged. The Examiner agrees with the Applicant that claims 1-19 and 23-27 read on the elected species. Claims 20-22 are withdrawn from consideration as being drawn to a non-elected species.

Specification

The disclosure is objected to because of the following informalities: In the specification, on page 8, paragraph {0019}, line 8, delete "is".

Appropriate correction is required.

Claim Objections

Claim 18 is objected to because of the following informalities: Claim 18 is dependent upon itself. The Examiner has assumed that it should be dependent upon claim 15. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "the catheter is a dialysis catheter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 12, 14, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman (4,524,805). Hoffman discloses a valve apparatus comprising a first flexible member (10) extending across a first lumen through which a flow of materials is to be controlled, the first flexible member including a plurality of first movable elements (20,22) formed on opposite sides of at least one first slit (19) extending through the first flexible member, the first movable elements maintained in a closed position until a predetermined amount of pressure is applied to the elements, in which case the movable elements are opened to permit fluid flow. In the device of Hoffman the first movable elements are biased towards a closed position by the resilience of the material of the first flexible members, the first slit is linear and parallel to the major axis of the first flexible member. The device also includes biasing members (24,26) coupled to the first flexible member substantially parallel to the first slit and the device being permanently sealed around the entire perimeter of the lumen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7,9-11,13,15-17, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (4,524,805) in view of Powers et al. (5,810,789). Hoffman discloses a valve apparatus that includes all of the limitations as recited in claim 1. Hoffman does not disclose to add a housing attached to a dual lumen catheter with a valve apparatus in each lumen to regulate the fluid flow. Powers et al. discloses a dual lumen catheter attached to a housing (figure 4) and a catheter with two housings, each housing having their own lumen (figure 1). Providing additional flexible members,

movable elements, and biasing members is simply duplicating the device of Hoffman. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the valve apparatus of Hoffman with the dual lumen catheter of Powers et al. to provide a catheter that can regulate flow to and from the body.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (4,524,805) in view of Ryan et al. (6,099,505). Hoffman discloses a device that includes all of the limitations as recited in claim 3. Hoffman does not disclose to include another pair of slits intersecting at the end of the first slit. Ryan et al. discloses a valve assembly with an automatic valve that includes a second pair of slits (162b, 162c) that intersect at the end of the first slit (162a). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the slits of Hoffman with the slit of Ryan et al. to make a valve that has better sealing capability.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman and Powers et al. as applied to claim 15 above, and further in view of Ryan et al. Hoffman and Powers et al. disclose a device that includes all of the limitations as recited in claim 15. Hoffman and Powers et al. do not disclose to include another pair of slits intersecting at the end of the first slit. Ryan et al. discloses a valve assembly with an automatic valve that includes a second pair of slits (162b, 162c) that intersect at the end of the first slit (162a). Ryan et al. do not disclose to make the second pair of slits substantially perpendicular to the first pair of slits. However, this limitation is deemed a matter of design choice because the Applicant has not disclosed that the angle of the slits solves any stated problem or is for any particular purpose.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the slits of Hoffman with the slit of Ryan et al. to make a valve that has better sealing capability.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2004/0102738 to Dikeman et al. discloses a pressure actuated flow control
JP0938198 to Takane discloses a dual lumen catheter with two check valves
US 4,502,502 to Krug discloses an overpressure safety valve

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Stigell